2800 Rockcreek Parkway
Kansas City, MO 64117
816.201.1024 Tel
816.474.1742 Fax

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Karen DeSalvo, MD
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
RE: *Comments on 2016 Interoperability Standards Advisory*
<Submitted Electronically>

Dear Dr. DeSalvo,

On behalf of Cerner, I am writing to provide comment on the open draft of the 2016 Interoperability Standards Advisory (2016 ISA). We appreciate the efforts of you and your team to improve on the ISA to help make this a valuable document for the industry to the best available interoperability standards and implementation specifications.

Cerner associates participated in the collaborative efforts led by the Electronic Health Record Association (EHRA) in response to the draft 2016 ISA. We largely support and endorse the EHRA-submitted comments relative to the assumption such an Advisory is valuable and refer to their response for more detailed considerations; however, we are compelled to respond individually to urge you and your team to consider the following general concerns.

As we also indicated in our response to the 2015 ISA, standards must not be considered in the abstract, but rather as attached to a "problem to be solved" or to an identified goal. We appreciate the adjustments made to the 2016 ISA to improve alignment with this objective. We remain concerned though that this has not be fully addressed. For example, the interoperability need of documenting care plans does not recognize the different environments within a documented care plan needs to be maintained. While for simple cases where few providers are involved the proposed standards would be adequate, more complex coordination of care across multiple providers in a heterogeneous environment would likely require a different approach and is very much in an exploratory phase. These types of variances must be recognized to help set expectations about the applicability of the standards.

In case of the proposed vocabulary standards it appears that while the use case is more clear, the proposed standards are not specific enough. For example, referencing SNOMED-CT for allergic reactions requires identification of the subset within SNOMED-CT that represent those allergic reactions.

We respectfully would like to reiterate our perspective voiced in our response to the 2015 ISA and in other fora that arriving at the most appropriate standards for national endorsement that drive consistency and ease of wide-spread interoperability, is primarily based on the experience of operational "data sharing networks" that agree to solve the critical interoperability goals, thus can validate the value, standards, and technology to realize those interoperability goals. Once the pilots are proven, additional market players who are willing to deploy can be included for a broad rollout. After being proven through a broad rollout, the standards can be considered for national endorsement and regulatory binding.

We appreciate the increased focus on emerging standards that can help stakeholders focus their efforts to help mature the most promising of those. To that end we encourage ONC to expand this to also identify based on industry feedback where clear interoperability needs exist but where there may be a gap in standards, although more likely implementation guidance. An example may be the closed loop referral process where there is a need for improved interoperability, some standards exist, but the full loop is not yet supported with a cohesive implementation guide. Another may be the convergence of clinical decision support and quality measure standards that support spectrum of clinical decision support and quality measure reporting use cases.

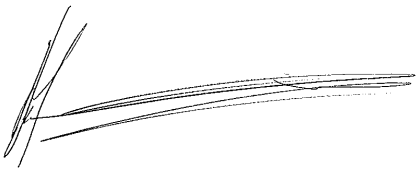
We also appreciate the introduction of the informative characteristics that can aid in assessing fit for purpose, maturity, and adoptability. We want to emphasize suggestions made in the EHRA response that further work is required to define and measure some of these characteristics. In particular:

- The Standards Maturity Process characteristic creates an ambiguous understanding of a standard's stability as the different review and publication processes seem to be mixed together, rather than harmonized along common criteria. We suggest to establish a common measure.
- The Adoption Level criterion is lacking measurable data and/or sources to confirm the estimates. We suggest simplifying the measure until better data is available to justify this level of precision.

To support fully the future for health IT, any interoperability standards bound by regulation to certification should be focused and associated with identified goals; driven by the private market in a voluntary manner that best supports pilot experimentation and maturation; and staged toward broader adoption.

All of us at Cerner compliment the federal government's efforts and willingness to approach this critical topic thoughtfully and comprehensively. Please do not hesitate to contact me if we can be of further assistance.

Sincerely,



Hans J. Buitendijk
Senior Expert R&D
Cerner Corporation
hans.buitendijk@cerner.com
610.219.2087